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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/937,678

09/28/2001

Eric Goutay

PF 100 PCT US

5103

25666

7590

05/26/2005

THE FIRM OF HUESCHEN AND SAGE
500 COLUMBIA PLAZA
350 EAST MICHIGAN AVENUE
KALAMAZOO, MI 49007

EXAMINER

YOUNG, MICAH PAUL

ART UNIT

PAPER NUMBER

1618

DATE MAILED: 05/26/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/937,678

Applicant(s)

GOUTAY ET AL.

Examiner

Micah-Paul Young

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1618

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 March 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 26-44 and 51 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 26-44 and 51 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Acknowledgement of Papers Received: Amendment/Response filed 3/8/05.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all

obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. Claims 26-44, and 51 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combined disclosures of Derrieu et al (USPN 5,527,783 hereafter 783) and Allen, Jr. et al (USPN 5,595,761 hereafter '761). The claims are drawn to a fast dissolving micro-porous structure.

4. The '783 patent discloses a solid composition based on plants, comprised of an active principle, diluents, binders, coloring and flavors (col. 4, lin. 7-12). The diluents of preference include lactose and mannitol (col. 4, lin. 27-28). The binders include gums such as gum Arabic, alginates, pectins, gelatin, xanthan gum, dextrin and polyvinylpyrrolidone (col. 4, lin 29-39). The additives used in the reference invention are those normally used in the pharmaceutical and food industry and are compatible with the active principles present (col. 4, lin. 39-43). The reference is however silent to the inclusion of a specific pharmaceutical actives. The reference is also silent to the density and dissolution time of the structure.

5. The '761 patent discloses a fast dissolving micro-porous composition comprising gelatin, and other components such as diluents, colors, flavors and binders (col. 6, lin. 60-65). The

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composition included alginic acid, polyvinylpyrrolidone, mannitol, and organic acids (col. 7, lin. 1-10). Further the composition has a density range of 0.1g/ml to 0.6g/ml (col. 4, lin. 1-28), and dissolution below 10 seconds (*Ibid.*). It would have been obvious to include the components of plant origin into the formulation of '761 in order to modulate the dissolution rate. The inclusion of the maltodextrins of '783 would have been well within the level of skill in the art.

6. Regarding the limitations reciting specific concentrations, it is the position of the examiner that such limitations do not impart patentability. The '761 patent discloses carriers in concentration above 60%, and very low concentrations of binding agents (examples). Though not every concentration is disclosed, the general conditions of the claims are met. Applicant is reminded that where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *See In re Aller*, 220 F.2d 454 105 USPQ 233, 235 (CCPA 1955).

7. Furthermore the claims differ from the reference by reciting various concentrations of the active ingredient(s). However, the preparation of various compositions having various amounts of the active is within the level of skill of one having ordinary skill in the art at the time of the invention. It has also been held that the mere selection of proportions and ranges is not patentable absent a showing of criticality. *See In re Russell*, 439 F.2d 1228 169 USPQ 426 (CCPA 1971).

8. With these things in mind one of ordinary skill in the art would have been motivated to combine the polysaccharides of '783 with the components and formulation of '761 in order to impart a sweeter flavor onto the formulation. It would have been obvious to combine these

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teachings and suggestions with an expected result of an effervescent formulation useful in delivering active agents.

Response to Arguments

9. Applicant's arguments filed 3/8/05 have been fully considered but they are not persuasive. Applicant argues that:

a. These exists no motivation to combine the '783 patent with the '761 patent.

10. Regarding this argument it is the position of the Examiner that there does in fact exist a motivation to combine the two references. Applicant sites that there is no mention of polymers of a plant origin in the '761 reference nor are the polymers of plant origin mentioned or exemplified in the reference. The Examiner directs Applicant's attention to col. 5, lin. 1-15 of the '761 reference where the reference teaches that in addition to or in lieu of gelatins useful for the primary support component may be comprises of cellulose derivatives, which are of plant origin. With this suggestion, one of ordinary skill in the art would be motivated to combine the structure of '783 with the formulation of '761. The artisan would have been motivated to include the polymer structure of '783 into the quick release formulation of '761 in order to impart stability and enhance mucosal absorption of the overall formulation. The '783 reference discloses a porous, plant originated polymer matrix for pharmaceutical agents that includes binders and disintegrants. The '761 reference discloses a fast dissolving porous carrier matrix for pharmaceutical agents, where the source material can be cellulose derivatives. Regarding the density, applicant is requested to provide evidence of criticality to this feature. The prior art formulation meets the basic limitations of the claims and any manipulations of the claims would

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be well within the level of skill within the art. Barring a showing of criticality to those features and a showing of unexpected results, the claims will remain obviated.

11. Further the Office does not have the facilities for examining and comparing applicant's product with the product of the prior art in order to establish that the product of the prior art does not possess the same material structural and functional characteristics of the claimed product. In the absence of evidence to the contrary, the burden is upon the applicant to prove that the claimed products are functionally different than those taught by the prior art and to establish patentable differences. *See Ex parte Phillips*, 28 U.S.P.Q.2d 1302, 1303 (PTO Bd. Pat. App. & Int. 1993), *Ex parte Gray*, 10 USPQ2d 1922, 1923 (PTO Bd. Pat. App. & Int.) and *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977).

12. With these things in mind the claims remain obviated by the prior art.

Conclusion

13. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Micah-Paul Young whose telephone number is 571-272-0608.

The examiner can normally be reached on M-F 7:00-4:30 every other Monday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Micah-Paul Young
Examiner
Art Unit 1618

MP Young

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
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